

What is claim is:

1. Use of a pharmaceutical composition consisting of fluvastatin or pitavastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier for the preparation of a medicament for the prevention or treatment of metabolic syndrome.
2. Use of a pharmaceutical composition according to claim 1 for the prevention or treatment of metabolic syndrome.
3. Use according to anyone of claims 1-2 wherein the metabolic syndrome is associated with resistance to insulin-mediated glucose uptake, glucose intolerance, hyperinsulemia, increased LDL-cholesterol, increased VLDL and triglycerides, decreased HDL-cholesterol, increased plasminogen activator inhibitor-1 (PAI-1) levels and hypertension.
4. Use according to anyone of claims 1-2 wherein the metabolic syndrome is characterized by three or more of the following criteria:
  1. Abdominal obesity: waist circumference >102 cm in men and >88 cm in women
  2. Hypertriglyceridemia:  $\geq 150$  mg/dl (1.695 mmol/l)
  3. Low HDL cholesterol: <40 mg/dl (1.036 mmol/l) in men and <50 mg/dl (1.295 mmol/l) in women
  4. High blood pressure:  $\geq 130/85$  mmHg
  5. High fasting glucose:  $\geq 110$  mg/dl ( $\geq 6.1$  mmol/l).
5. Use according to anyone of claims 1-2 wherein the metabolic syndrome is characterized by diabetes, impaired glucose tolerance, impaired fasting glucose, or insulin resistance plus two or more of the following abnormalities:
  - 1 High blood pressure:  $\geq 160/90$  mmHg
  - 2 Hyperlipidemia: triglyceride concentration  $\geq 150$  mg/dl (1.695 mmol/l) and/or HDL cholesterol <35 mg/dl (0.9 mmol/l) in men and <39 mg/dl (1.0 mmol/l) in women
  - 3 Central obesity: waist-to-hip ratio of >0.90 in men or >0.85 in women and/or BMI >30 kg/m<sup>2</sup>

4. Microalbuminuria: urinary albumin excretion rate  $\geq 20$   $\mu\text{g}/\text{min}$  or an albumin-to-creatinine ratio  $\geq 20$   $\text{mg}/\text{g}$ .
6. Use according to anyone of claims 1-2 wherein the metabolic syndrome is characterized by three or more of the following criteria:  
triglycerides  $> 150$   $\text{mg}/\text{dl}$ , systolic blood pressure (BP)  $\geq 130$   $\text{mm Hg}$  or diastolic BP  $\geq 85$   $\text{mm Hg}$  or on antihypertensive treatment, high-density lipoprotein cholesterol  $< 40$   $\text{mg}/\text{dl}$ , fasting blood sugar (FBS)  $> 110$   $\text{mg}/\text{dl}$ , and a BMI  $> 28.8$   $\text{k}/\text{m}^2$ .
7. A pharmaceutical composition for the prevention or treatment of metabolic syndrome consisting of fluvastatin or pitavastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier.
8. Pharmaceutical composition according to claim 7 wherein the metabolic syndrome is associated with resistance to insulin-mediated glucose uptake, glucose intolerance, hyperinsulemia, increased LDL-cholesterol, increased VLDL and triglycerides, decreased HDL-cholesterol, increased plasminogen activator inhibitor-1 (PAI-1) levels and hypertension.
9. Pharmaceutical composition according to claim 7 wherein the metabolic syndrome is characterized by three or more of the following criteria:
1. Abdominal obesity: waist circumference  $> 102$   $\text{cm}$  in men and  $> 88$   $\text{cm}$  in women
  2. Hypertriglyceridemia:  $\geq 150$   $\text{mg}/\text{dl}$  ( $1.695$   $\text{mmol}/\text{l}$ )
  3. Low HDL cholesterol:  $< 40$   $\text{mg}/\text{dl}$  ( $1.036$   $\text{mmol}/\text{l}$ ) in men and  $< 50$   $\text{mg}/\text{dl}$  ( $1.295$   $\text{mmol}/\text{l}$ ) in women
  4. High blood pressure:  $\geq 130/85$   $\text{mmHg}$
  5. High fasting glucose:  $\geq 110$   $\text{mg}/\text{dl}$  ( $\geq 6.1$   $\text{mmol}/\text{l}$ ).
10. Pharmaceutical composition according to claim 7 wherein the metabolic syndrome is characterized by diabetes, impaired glucose tolerance, impaired fasting glucose, or insulin resistance plus two or more of the following abnormalities:
1. High blood pressure:  $\geq 160/90$   $\text{mmHg}$

- 2      Hyperlipidemia: triglyceride concentration  $\geq 150$  mg/dl (1.695 mmol/l) and/or HDL cholesterol  $< 35$  mg/dl (0.9 mmol/l) in men and  $< 39$  mg/dl (1.0 mmol/l) in women
- 3      Central obesity: waist-to-hip ratio of  $> 0.90$  in men or  $> 0.85$  in women and/or BMI  $> 30$  kg/m<sup>2</sup>
- 4      Microalbuminuria: urinary albumin excretion rate  $\geq 20$   $\mu$ g/min or an albumin-to-creatinine ratio  $\geq 20$  mg/g.

11. Pharmaceutical composition according to claim 7 wherein the metabolic syndrome is characterized by three or more of the following criteria:

triglycerides  $> 150$  mg/dl, systolic blood pressure (BP)  $\geq 130$  mm Hg or diastolic BP  $\geq 85$  mm Hg or on antihypertensive treatment, high-density lipoprotein cholesterol  $< 40$  mg/dl, fasting blood sugar (FBS)  $> 110$  mg/dl, and a BMI  $> 28.8$  kg/m<sup>2</sup>.

12. A method for the prevention or treatment of metabolic syndrome comprising in administering a pharmaceutical composition to the patient, wherein the pharmaceutical composition consists of fluvastatin or pitavastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier.

13. Method according to claim 12 wherein the metabolic syndrome is associated with resistance to insulin-mediated glucose uptake, glucose intolerance, hyperinsulemia, increased LDL-cholesterol, increased VLDL and triglycerides, decreased HDL-cholesterol, increased plasminogen activator inhibitor-1 (PAI-1) levels and hypertension.

14. Method according to claim 12 wherein the metabolic syndrome is characterized by three or more of the following criteria:

1.      Abdominal obesity: waist circumference  $> 102$  cm in men and  $> 88$  cm in women
2.      Hypertriglyceridemia:  $\geq 150$  mg/dl (1.695 mmol/l)
3.      Low HDL cholesterol:  $< 40$  mg/dl (1.036 mmol/l) in men and  $< 50$  mg/dl (1.295 mmol/l) in women
4.      High blood pressure:  $\geq 130/85$  mmHg
5.      High fasting glucose:  $\geq 110$  mg/dl ( $\geq 6.1$  mmol/l).

15. Method according to claim 12 wherein the metabolic syndrome is characterized by diabetes, impaired glucose tolerance, impaired fasting glucose, or insulin resistance plus two or more of the following abnormalities:

- 1 High blood pressure:  $\geq 160/90$  mmHg
- 2 Hyperlipidemia: triglyceride concentration  $\geq 150$  mg/dl (1.695 mmol/l) and/or HDL cholesterol  $< 35$  mg/dl (0.9 mmol/l) in men and  $< 39$  mg/dl (1.0 mmol/l) in women
- 3 Central obesity: waist-to-hip ratio of  $> 0.90$  in men or  $> 0.85$  in women and/or BMI  $> 30$  kg/m<sup>2</sup>
- 4 Microalbuminuria: urinary albumin excretion rate  $\geq 20$   $\mu$ g/min or an albumin-to-creatinine ratio  $\geq 20$  mg/g.

16. Method according to claim 12 wherein the metabolic syndrome is characterized by three or more of the following criteria:

triglycerides  $> 150$  mg/dl, systolic blood pressure (BP)  $\geq 130$  mm Hg or diastolic BP  $\geq 85$  mm Hg or on antihypertensive treatment, high-density lipoprotein cholesterol  $< 40$  mg/dl, fasting blood sugar (FBS)  $> 110$  mg/dl, and a BMI  $> 28.8$  k/m<sup>2</sup>.